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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,511	07/23/2004	Hirosige Nakatsuka	SAEG115.002APC	5949
20995	7590	01/30/2006		
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER THEXTON, MATTHEW	
			ART UNIT	PAPER NUMBER
			1714	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/502,511	Applicant(s) NAKATSUKA ET AL.	
	Examiner Matthew A. Thexton	Art Unit 1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Text of Title 35 USC not Cited

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Version

The claims as amended in the paper filed 2006 January 9 have been examined.

Claims Analysis

Claims 1-12 have been canceled.

Independent claim 13 is directed to methods of blocking or reducing adverse effects of x-rays, gamma rays and/or electron beams to a subject comprising:

“determining” a subject will be exposed; and

“protecting” the subject with material comprising at least one member from
the group consisting of collagens, keratins, silk fibroins and their
derivatives.

Dependent claims 14-19 further require:

(14/13) that the member “is administered to, mixed with, coated on or
immobilized on a subject”;

(15/13) that “a subject” is protected by “a radioprotective plastic product,
radioprotective film, radioprotective sheet, radioprotective coating agent, radioprotective

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cosmetic product, or radioprotective fiber comprising at least one member selected from the group...is used to protect a subject”;

(16/15) that “a product” comprising the member “is place over, applied to or administered to a subject”;

(17/13) that the member “is present inside a subject or inside a surface layer of a subject in a total amount of 0.05 wt.% to 40 wt%”;

(18/13) that “the subject” is selected from the group consisting of “agricultural products, marine products, foods, domestic animals, pets, electronic precision instruments, textiles, medical and experimental materials”;

(19/13) “wherein the subject is a human.”

Such is interpreted to encompass “wearing” silk and silk blends, leather, or wool, wool blends, and other fur clothing worn by medical workers (doctors, dentists, chiropractors), pets, humans, and clothing worn by models which are experiments of design, as well as “using” molded articles which may be employed in apparatus without limitation including medical, experimental, measuring, and household. The claims do not recite any limitations on levels of radiation exposure and it is noted that such radiation is present all the time, particularly gamma rays and x-rays are present from terrestrial and cosmic sources as a background all the time. Therefore, the step of “determining that a subject will be exposed to said x-rays, gamma rays and/or electron beams” is merely acknowledging that one exists on Earth, and thus this step is of no patentable significance; whether one “determines” such exposure or not, it is inherent. Nor could the step of “protecting” be distinguished from the steps of any actor who omits

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the step of “determining...” since “protecting” requires merely draping oneself or objects with silk, silk blend, leather, wool, wool blend, or other fur clothing as is performed routinely and intentionally, per se.

Claim Objections

Claim 13 is objected to because of the following informalities: In the penultimate line, “at least” is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not indicated where in the specification there is support for, nor has such been located, the step of “determining that a subject will be exposed to said x-rays, gamma rays and/or electron beams.”

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of these claims refers to “a subject” while the claim from which they depend already recites “a subject.” It is unclear if Applicant intends to introduce a new subject or intends to rely upon the antecedence of ‘the’ subject of claim 13.

Claim Rejections

Claims 13-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Official Notice of commercially available materials comprising collagen, keratin, or silk.

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

The rejection set forth in the previous Office action is incorporated here by reference. To the extent that the step of “determining...” is not explicitly disclosed it is asserted that many knowledgeable persons are aware that in fact background radiation has been determined to exist and proceed to wear materials as defined by the claims, thus anticipating the claimed subject matter.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pauly et al. (WO 01/45661-A2, as evidenced by US 2003/0091518-A1). All references to this document will be to the US version, aka ‘518.

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

The rejection set forth in the previous Office action is incorporated here by reference. To the extent that the step of “determining...” is not explicitly disclosed it is asserted that many knowledgeable persons are aware that in fact background radiation has been determined to exist and proceed to wear materials as defined by the claims, thus anticipating the claimed subject matter.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Urita (JP 10-338615-A, as evidenced by the USPTO obtained translation).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

The rejection set forth in the previous Office action is incorporated here by reference. To the extent that the step of “determining...” is not explicitly disclosed it is asserted that many knowledgeable persons are aware that in fact background radiation has been determined to exist and proceed to wear materials as defined by the claims, thus anticipating the claimed subject matter.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Natsume et al. (JP 01-280465-A, as evidenced by the USPTO obtained translation).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

The rejection set forth in the previous Office action is incorporated here by reference. To the extent that the step of “determining...” is not explicitly disclosed it is asserted that many knowledgeable persons are aware that in fact background radiation has been determined to exist and proceed to wear materials as defined by the claims, thus anticipating the claimed subject matter.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Erwin (US 4946450).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

Reference '450 discloses materials containing collagen, which may be used for therapeutic eye shield. Radioprotective property is inherent and overtly ongoing.

The rejection set forth in the previous Office action is incorporated here by reference. To the extent that the step of “determining...” is not explicitly disclosed it is asserted that many knowledgeable persons are aware that in fact background radiation has been determined to exist and proceed to wear materials as defined by the claims, thus anticipating the claimed subject matter.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sano et al. (US 5718954-A).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

The rejection set forth in the previous Office action is incorporated here by reference. To the extent that the step of “determining...” is not explicitly disclosed it is asserted that many knowledgeable persons are aware that in fact background radiation has been determined to exist and proceed to wear materials as defined by the claims, thus anticipating the claimed subject matter.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sakaki et al. (US 5587411-A).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

The rejection set forth in the previous Office action is incorporated here by reference. To the extent that the step of “determining...” is not explicitly disclosed it is asserted that many knowledgeable persons are aware that in fact background radiation has been determined to exist and proceed to wear materials as defined by the claims, thus anticipating the claimed subject matter.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sato et al. (US 4638024).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

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The rejection set forth in the previous Office action is incorporated here by reference. To the extent that the step of "determining..." is not explicitly disclosed it is asserted that many knowledgeable persons are aware that in fact background radiation has been determined to exist and proceed to wear materials as defined by the claims, thus anticipating the claimed subject matter.

Response to Arguments

Applicant's arguments filed 2006 January 9 have been fully considered but they are not persuasive. Applicant summarizes (page 5, last paragraph, of response) that the references nowhere teach or suggest that collagens, keratins, and silk fibroin have protective effects against the recited radiation and therefore do not suggest or make obvious to one of ordinary skill in the art to determine whether a subject will be exposed and then, based on that determination, block or reduce the adverse effects of the radiation. Full response to this is found in the section ***Claims Analysis*** and in the statements of rejection hereinabove.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew A. Thexton whose telephone number is 571-272-1125. The examiner can normally be reached on Tuesday-Friday, 9:30 to 7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasudevan S. Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew A. Thexton
Primary Examiner
Art Unit 1714
matthew.thexton@uspto.gov